

AMENDED CLAIMS

1.-21. (Canceled)

22. (Withdrawn) A method of sterilizing a polymeric material for use in a body of a mammal comprising irradiating said polymeric material at a temperature below 25 °C.

23. (Withdrawn) The method of claim 22 wherein the polymeric material further comprises a therapeutically active agent.

24. (Withdrawn) The method of claim 22 wherein said temperature is below about 15 °C.

25. (Withdrawn) The method of claim 22 wherein said temperature is below about 10 °C.

26. (Withdrawn) The method of claim 22 wherein said temperature is below about 5 °C.

27.-69 (Canceled)

70. (Currently amended) A gamma irradiated sterilized therapeutic composition comprising microparticles comprising at least one polymer and at least one therapeutically active agent wherein said microparticles are gamma irradiated at a temperature of less than 5 C. to thereby provide microparticles that are less aggregated when gamma irradiated at less than 5C than when the same therapeutic composition is gamma irradiated for the same time and at the same dose of gamma radiation at a temperature greater than 5 C.

71. (Previously presented) The gamma irradiated sterilized therapeutic composition according to claim 70 wherein said at least one polymer is poly(lactide-co-glycolide) (PLGA) or polylactic acid (PLA).

72. (Previously presented) The gamma irradiated sterilized therapeutic composition according to claim 71 wherein said at least one polymer is PLGA.

73. (Previously presented) The gamma irradiated sterilized therapeutic composition according to claim 70 wherein said at least one therapeutically active agent is tazarotene.

74. (Previously presented) The gamma irradiated sterilized therapeutic composition according to claim 70 wherein said dose of gamma radiation is between 2.5 and 4.5 Mrad.

75. (Previously presented) The gamma irradiated sterilized therapeutic composition according to claim 70 wherein said sterilized therapeutic composition is a freeze-dried powder.

76. (Previously presented) The gamma irradiated sterilized therapeutic composition according to claim 70 wherein said microparticles are less aggregated when gamma irradiated at less than 5C than when the same therapeutic composition is gamma irradiated for the same time and at the same dose of gamma radiation at a temperature greater than 5 C.

77. (Previously presented) The gamma irradiated sterilized therapeutic composition according to claim 70 wherein said therapeutic composition is a sustained delivery composition.

78. (Previously presented) The gamma irradiated sterilized therapeutic composition according to claim 70 wherein said microparticles have an average size less than 100 micrometers in diameter.

79. (Currently amended) A gamma irradiated sterilized therapeutic composition according to claim 70 comprising microparticles having an average size less than 100 micrometers in diameter comprising PLGA and one therapeutically active agent wherein said microparticles are gamma irradiated at a temperature of less than 5 C. to thereby provide microparticles that are less aggregated ~~when gamma irradiated at less than 5°C~~ than when the same therapeutic composition is gamma irradiated for the same time and at the same dose of gamma radiation at a temperature greater than 5 C.

80. (Previously presented) The gamma irradiated sterilized therapeutic composition according to claim 79 wherein said at least one therapeutically active agent is tazarotene.

81. (Previously presented) The gamma irradiated sterilized therapeutic composition according to claim 79 wherein said dose of gamma radiation is between 2.5 and 4.5 Mrad.

82. (Previously presented) The gamma irradiated sterilized therapeutic composition according to claim 79 wherein said sterilized therapeutic composition is a freeze-dried powder.

83. (Previously presented) The gamma irradiated sterilized therapeutic composition according to claim 70 wherein said sterilized therapeutic composition is a sustained delivery composition.

84. (Currently amended) A gamma irradiated sterilized therapeutic composition comprising microparticles comprising PLGA and tazarotene wherein said microparticles are gamma irradiated at a temperature of less than 5°C. to thereby provide microparticles that are less aggregated when gamma irradiated at less than 5°C than when the same therapeutic composition is gamma irradiated for the same time and at the same dose of gamma radiation at a temperature greater than 5 C.

85. (Previously presented) The gamma irradiated sterilized therapeutic composition according to claim 84 wherein said microparticles have an average size less than 100 micrometers in diameter.

86.-87. (Canceled)

88. (New) A composition for therapeutic use, the composition comprising gamma irradiated sterilized therapeutic composition comprising polymeric microparticles and further comprising at least one polymer and at least one therapeutically active agent the

composition obtained by a process comprising the following step: irradiating said polymeric microparticles at a temperature of less than 5 C. to thereby provide microparticles that are less aggregated than when the same therapeutic composition is gamma irradiated for the same time and at the same dose of gamma radiation at a temperature greater than 5 C.

89. (New) The gamma irradiated sterilized therapeutic composition according to claim 88 wherein said at least one polymer is poly(lactide-co-glycolide) (PLGA) or polylactic acid (PLA).

90. (New) The gamma irradiated sterilized therapeutic composition according to claim 88 wherein said at least one polymer is PLGA.

91. (New) The gamma irradiated sterilized therapeutic composition according to claim 88 wherein said dose of gamma radiation is between 2.5 and 4.5 Mrad.

92. (New) The gamma irradiated sterilized therapeutic composition according to claim 88 wherein said sterilized therapeutic composition is a freeze-dried powder.

93. (New) The gamma irradiated sterilized therapeutic composition according to claim 88 wherein said microparticles have an average size less than 100 micrometers in diameter.

94. (New) The gamma irradiated sterilized therapeutic composition according to claim 88 wherein said at least one therapeutically active agent is tazarotene.

95. (New) A method for making a composition for therapeutic use, the composition comprising a gamma irradiated sterilized therapeutic composition comprising polymeric microparticles and further comprising at least one polymer and at least one therapeutically active agent the composition obtained by a process comprising the step of irradiating said polymeric microparticles at a temperature of less than 5 C. to thereby provide microparticles that are less aggregated than when the same therapeutic

composition is gamma irradiated for the same time and at the same dose of gamma radiation at a temperature greater than 5 C.

96. (New) The gamma irradiated sterilized therapeutic composition according to claim 95 wherein said at least one polymer is poly(lactide-co-glycolide) (PLGA) or polylactic acid (PLA).

97. (New) The method according to claim 96 wherein said at least one polymer is PLGA.

98. (New) The method according to claim 97 wherein said dose of gamma radiation is between 2.5 and 4.5 Mrad.

99. (New) The method according to claim 98 wherein said sterilized therapeutic composition is a freeze-dried powder.

100. (New) The method according to claim 99 wherein said microparticles have an average size less than 100 micrometers in diameter.

101. (New) The method according to claim 100 wherein said at least one therapeutically active agent is tazarotene.